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SUMMARY OF SAFETY AND SUBSTANTIAL EQUIVALENCE

1. Applicant's Name and Address

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Contact Person

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2. Identification of device

Common Name:	Soft Contact Lens
Trade Name:	BIOMEDICS® 52 1-Day (ocufilcon B) Soft (Hydrophilic) UV Blocking Contact lenses
Classification:	Daily Wear Soft (hydrophilic) Contact Lens
Device classification:	Class II (21 CFR 886.5925 (b) (1))

3. Description of device

The BIOMEDICS® 52 1-Day (ocufilcon B) Soft (Hydrophilic) UV Blocking Contact lenses are available with ultraviolet absorbing additive (benzophenone based):

- in the power range of -10.00 to +6.00 diopters for sphere
- in the cylinder power range pl to -6.00D cylinder
- with center thickness from 0.025mm to 0.27mm
- with base curves of 8.00mm to 9.20mm
- with diameter of 12.00mm to 18.00mm.

This lens material, design, cast molding manufacturing and sterilization process is equivalent to BIOMEDICS® 52 1-Day (ocufilcon B) Soft (Hydrophilic) UV Blocking Contact lenses described in submission PMA890023/S4,S6 and S7, 510(K) K003136.

4. Intended use

Spherical:

BIOMEDICS® 52 1-Day (ocufilcon B) Soft (Hydrophilic) UV Blocking Contact lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of 2.00 diopters that does not interfere with visual acuity.

Ocular Sciences <i>(ocufilcon B) soft (hydrophilic)</i> <i>contact lens</i>	510(K) PREMARKET NOTIFICATION SUMMARY OF SAFETY AND SUBSTANTIAL EQUIVALENCE	Reference OSL52 Section : 3 Version : 1 Page : 2 / 8
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Toric:

BIOMEDICS® 52 1-Day (ocufilcon B) Soft (Hydrophilic)UV Blocking Contact lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of up to 10.00 diopters.

The lens may be prescribed for Daily Wear in not- aphakic persons. The eyecare practitioner may prescribe the contact lens for wither single use disposable wear.

The BIOMEDICS® 52 1-Day (ocufilcon B) Soft (Hydrophilic) UV Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

5. Predicate devices

The predicate lenses were selected to address: material (FDA Group IV: high water, ionic polymer), intended use (daily wear) and lens designs (sphere, toric).

Lens material, spherical and toric lens design and intended use:

BIOMEDICS® 52 1-Day (ocufilcon B) Soft (hydrophilic) UV Blocking Contact lenses, FDA Group IV, high water content, ionic soft contact lenses for daily wear marketed internationally by OCULAR SCIENCES Inc. under K003136.

6. Characteristics

The characteristics of the BIOMEDICS® 52 1-Day (ocufilcon B) Soft (hydrophilic) UV Blocking Contact lenses are compared to the characteristics of the predicate device BIOMEDICS® 52 in the following table.

TABLE 1

Material and Parameter comparison		
	Predicate device BIOMEDICS® 52	Subject device BIOMEDICS® 52 1-Day
PRODUCTION METHOD	Cast molded process	Cast molded process
INTENDED USE	Daily wear Correction of ametropia	Daily wear Correction of ametropia
MATERIAL	ocufilcon B	ocufilcon B
Type	Group IV	Group IV
Color additive	Vat Blue 6 Dye 21 CFR 73.3119 CAS #130-20-1	Vat Blue 6 Dye 21 CFR 73.3119 CAS #130-20-1
UV additive	Yes	Yes
<i>Characteristics comparison</i>	<i>Labeled</i>	<i>Labeled</i>
Water Content % @ 20°C	52	52
Refractive Index @ 20°C	1.41	1.41
Dk permeability, ISO 9913-1 Polarimetric method with edge correction @ 35°C x 10 ⁻¹¹ (cm ² /sec) (ml O ₂ /ml x mm Hg)	16.8	16.8
Light transmittance	Tv, % @ 20°C Illuminant A with a 2° observer (between 380 and 780 nm) 97.7% average	Tv, % @ 20°C Illuminant A with a 2° observer (between 380 and 780 nm) 97.7% average

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<i>Characteristics comparison, -300 D 40 lenses</i>	<i>Labeled</i>	<i>Labeled</i>
Base Curve, mm	8.70	8.70
Diameter, mm	14.20	14.20
Power, D	-3.00	-3.00

7. Non clinical studies

Non-clinical studies are summarized below:

Chemistry and leachability

- Material property data were generated on the BIOMEDICS® 52 and the BIOMEDICS® 52 1-Day lenses processed with the manufacturing process changes. The material properties were substantially equivalent.
- The lens care product manufacturers have previously shown compatibility of Group IV lenses with their products.
- The shelf life stability for BIOMEDICS® 52 1-Day lenses is based upon stability protocols included with this notification.
- Studies were conducted to determine the residual monomers on the subject device.

Toxicology, lenses materials

In accordance with the May 1994 Guidance Document for Daily Wear contact lenses, toxicology studies have been conducted on the BIOMEDICS® 52 1-Day containing UV blocker. The results are summarized below:

• Cytotoxicity Test:

Cytotoxicity Tests have been conducted on the subject device according to ISO 10993: Biological Evaluation of Medical Devices, Part 5: Tests for Cytotoxicity: In vitro Methods guidelines, was conducted on the test articles, to determine the potential for Cytotoxicity.

The negative controls and the positive controls performed as anticipated. Under the conditions of the study, the test articles were not cytotoxic.

• Acute Systemic Injection Test in the mouse:

An evaluation of the test articles for systemic toxicity in mice after a single intravenous administration or a single intraperitoneal administration has been conducted according to the ISO 10993: Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity.

No evidence of systematic toxicity was observed from the test article extracts. Each test article met the test requirements.

• Ocular Eye Irritation Test in the rabbit:

An evaluation of the ocular irritation of 0.9% NaCl of the subject article after a single instillation in the rabbit has been conducted according to ISO 10993: Biological Evaluation of Medical devices, Part 10: Tests for the Irritation and Sensitization.

No evidence of ocular irritation was observed in the rabbits. The test article extracts are not considered irritants to the ocular tissue of rabbits.

• 22-Day Ocular Eye Irritation Study in the rabbit

For the evaluation of the safety of the subject device with regard to ocular irritation a test for ocular irritation was conducted in rabbits in accordance with ISO 9394:1997(E). Lens wear was a minimum of 7 hours for 21 consecutive days. On lens wear day 22, lenses were worn for a least 4 hours.

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Laboratory observations during the study included daily health observations, macroscopic eye examinations (during the last hour of lens wear), weekly biomicroscopic slit-lamp examinations and body weight observations.

Under the conditions of this study, eyes treated with test lenses were similar to the untreated control eyes.

Solution Compatibility

Microbiology: The lens care product manufacturers have established a reasonable assurance of disinfection efficacy of their care products with lens groups for which they are approved.

Non-clinical studies and manufacturing information provided by reference PMA890023 S4/S7 and K003136

- Cast molded manufacturing process
- Toxicology packaging materials
- Microbiology and sterilization

8. Clinical data

Clinical studies were performed to establish the safety and efficacy of the Biomedics® 52 1-Day lenses with an in-process manufacturing change. The purpose of the clinical investigation was to verify that the change made in the manufacturing process to an unextracted process, substantiated by safety toxicity testing data results, do not raise additional questions of safety or effectiveness.

The study was designed as an open-label, prospective, multi-center, concurrent cohort control, randomized clinical trial. Subjects were recruited based upon specified inclusion and exclusion criteria to assure that the appropriate subject population samples were included and inappropriate subjects were excluded. Scheduled follow-up visits were planned for the 1-Week, 2-Week and 4-Week visit intervals based upon the date the subject was dispensed the Test or Control lenses. No subjects were discontinued prior to completion in this investigation. No adverse events were reported for either the Test or Control cohort through the study period.

Thirty-six (36) subjects (72 eyes) were enrolled into the study at three (3) investigational sites. All of the 36 subjects were determined to be eligible to enter the study and were dispensed either the Test or the Control lenses based upon a randomization schedule provided to the site.

The distribution of age and gender of the subjects enrolled into the study by cohort is shown below.

Distribution of Age and Gender			
	Test	Control	Totals
Female Subjects	19	10	29
Male Subjects	5	2	7
Ratio F/M	3.8:1	5:1	4.1:1
Average Age (years)	36.0	38.8	36.9

Safety Results:

Safety is demonstrated if the test lens complications are substantially equivalent in frequency and severity to the control lens complications.

1. *Permanent decreases in BCVA:* There were no reports of 2-line decreases in best corrected Snellen visual acuity for any of the Test or Control cohort eyes.

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2. *Persistent corneal staining* of Grade 3 or 4 at two or more follow-up visits: There were no reports of Grade 3 or 4 staining for either the Test or the Control cohort eyes.
3. *Neovascularization* more than 1.5mm and/or more than 1.0mm in 3 or more quadrants: There was no neovascularization reported of greater than 1.5mm in any quadrant. The incidence of neovascularization reported for the Completed Test and Control cohort eyes remained stable throughout the period of the study.
4. *Persistent hyperemia* of Grade 3 or 4 at two or more follow-up visits: No Grade 3 or 4 limbal or bulbar hyperemia was reported during the period of the study for any Test or Control cohort eyes.
5. *Peripheral or central ulcerative keratitis*: No peripheral or central ulcerative keratitis was reported during the period of the study for any Test or Control cohort eyes.
6. *Infiltrates* of Grade 2 or worse: No infiltrates were reported during the period of the study for any Test or Control cohort eyes.
7. *Subjective symptoms, problems or complaints*: Subjective symptoms were reported for both the Test and the Control eyes over the course of the study. The areas where the Test and Control cohorts presented with differences were in discomfort and blurred vision.

Discomfort was reported more frequently and with greater severity for the Test cohort eyes with 12.5% of the follow-up examinations for Test eyes resulting in a report of discomfort with an average severity of 2.1 out of 4.0. This is in contrast to the Control cohort eyes where discomfort was reported for 7.3% of the follow-up examinations with an average severity of 1.1 out of 4.0.

Blurred vision was reported more frequently for the Control cohort eyes with 6.3% of the follow-up examinations for Control eyes resulting in a report of blurred vision with an average severity of 1.7 out of 4.0. This is in contrast to the Test cohort eyes where blurred vision was reported for 1.6% of the follow-up examinations with an average severity of 1.0 out of 4.0.

The findings for symptoms, problems and complaints do not indicate any safety issues with the Test lenses when compared to the Control lenses. The symptom of discomfort was not related to objective (slit lamp) findings for the Test cohort eyes and does not by itself indicate any safety concerns.

Both the Test and the Control cohort eyes had similar outcomes in the evaluation of the safety variables. Very few complications were reported during the study and most were mild and transient. Based upon the safety criteria established in the study protocol and reviewed above, the Test lens demonstrates equivalent safety when compared to the Control lens.

Visual Acuity Results:

The comparison of the beginning and ending lens visual acuities within and between the Test and the Control cohort eyes provides evidence that the Test lens is safe and effective with respect to lens visual acuity. Both the Test and Control lens visual acuities are essentially the same at the final examination.

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Proportion of Lens Visual Acuities
Dispensing Versus Final Examination

<u>Visit Sample Size</u>	<u>Dispensing</u>	<u>Final Visit</u>
Completed Test Eyes	48	46
Completed Control Eyes	24	24

Proportion of Lens Visual Acuities 20/30 or Better

<u>Eyes with VA of 20/30 or better</u>	<u>Dispensing</u>	<u>Final Visit</u>
Completed Test Eyes	100.0%	100.0%
Completed Control Eyes	95.8%	100.0%

Proportion of Lens Visual Acuities 20/20 or Better

<u>Eyes with VA of 20/20 or better</u>	<u>Dispensing</u>	<u>Final Visit</u>
Completed Test Eyes	83.3%	84.8%
Completed Control Eyes	54.2%	83.3%

Average Wearing Time:

Based upon the average lens wearing times reported by the Test and Control subjects, both cohorts were achieving acceptable and similar average daily wearing times. For the Test cohort the average wearing time was 12.8 hours per day to 13.2 hours per day over the period of the study. For the Control cohort the average wearing time was 13.1 hours per day to 13.3 hours per day over the period of the study.

Lens Deposits over course of the study:

Over the period of the study the Test and the Control cohort lenses were reported to have similar rates, Test 12.5% and Control 11.1%, with the Test eyes reporting 1.4% of the lenses as having medium deposits and the Control eyes only reporting light deposits.

Efficacy Summary:

1. *The proportion of subjects in each group (Test or Control) successfully completing the protocol specified study duration:* All of the Test and Control cohort subjects completed the 1 month study period. No subjects were discontinued for any reason.
2. *The percentage of lens visual acuities of 20/20 and the percentage of lens visual acuities of 20/30 or Better:* The percentage of Completed eyes reporting visual acuities of 20/20 or better at the final study visit was 84.8% for the Test cohort eyes and 83.3% for the Control cohort eyes. Both of these proportions are greater than those measured at the start of the study. The percentage of Completed eyes reporting visual acuities of 20/30 or better at the final study visit was 100% for the Test cohort eyes and 100% for the Control cohort eyes. The percentage of Test eyes reporting VAs of 20/30 at the final visit met the expectations set at the inception of the study.
3. Overall, the visual performance of the Test lens was similar to the performance of the Control lens.

Conclusions:

These conclusion are based upon the review of the data reported during the 1 month evaluation of the safety and efficacy of the Biomedics® 52 1-Day (ocufilcon B) soft (hydrophilic) contact lenses manufactured under a process change used following a daily disposable contact lens regimen.

The results of the slit lamp examinations indicate that the Test lens performs at least as well as the Control lens in terms of safety. Visual acuities and ocular health were all maintained during the study. Except for

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discomfort, most of the symptoms, problems and complaints were reported at similar rates between the Test and the Control cohorts. The completion of all of the subjects recruited for the study and the excellent visual acuity results demonstrate the efficacy of the Test lens during the study.

The difference in the reports and severity of the symptom discomfort also suggest that the Test lens is associated with excessive discomfort for some of the Test subjects. The findings of this study demonstrate that the Test lens performs equivalently in terms of safety and efficacy when compared to the Control lens cohort.

9. Conclusions drawn from studies

Validity of Scientific Data:

A contract laboratory using Good Laboratory Practices conducted the Toxicology studies. Chemistry leachables studies were conducted by Ocular Sciences, UK Ltd.

Substantial Equivalence:

Information provided in this 510(k) establishes that the Biomedics® 52 1-Day lenses are equivalent in optical, chemical and physical properties of the predicate devices and do not raise any questions of safety and effectiveness. Therefore, the device is substantially equivalent to the predicate devices, Biomedics® 52 1-Day (ocufilcon B) soft (Hydrophilic) UV blocking contact lenses under K003136.

Risk and Benefits:

The risks of the subject device are the same as those normally attributed to the wearing of soft (hydrophilic) contact lenses on a daily wear base. The benefits to the patient are the same as those for other soft (hydrophilic) contact lenses.

10. Route chosen in the Flow Chart for 510 (k) Daily Wear Contact Lens Materials Submission

FIGURE 1 [NEXT PAGE]

BIOMEDICS® 52 1-Day



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ocular Sciences, Inc.
c/o Richard E. Lippman, O.D., F.A.A.O.
Senior Consultant
Official Correspondent to Ocular Sciences, Inc.
R.P. Chiacchierini & Associates, LLC
17003 Horn Point Drive
Gaithersburg, MD 20878

JUN 04 2002

Re: K020389

Trade/Device Name: BIOMEDICS[®] 52 1-Day (ocufilcon B) Soft (hydrophilic) UV
Blocking Contact Lens for Daily Wear
(Spherical and Toric)

Regulation Number: 21 CFR 886.5925

Regulation Name: Soft (hydrophilic) Contact Lens

Regulatory Class: Class II

Product Code: LPL; MVN

Dated: May 2, 2002

Received: May 3, 2002

Dear Dr. Lippman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, reading "A. Ralph Rosenthal". The signature is written in a cursive, flowing style.

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATION FOR USE STATEMENT

SECTION 2 : INDICATIONS FOR USE STATEMENT

510(k) Number (if known) _____

Device Name:

Indications for Use:

Spherical:

BIOMEDICS® 52 1-Day (ocufilcon B) Soft (Hydrophilic) UV Blocking Contact lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of 2.00 diopters that does not interfere with visual acuity.

Toric:

BIOMEDICS® 52 1-Day (ocufilcon B) Soft (Hydrophilic) UV Blocking Contact lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of 10.00 diopters.

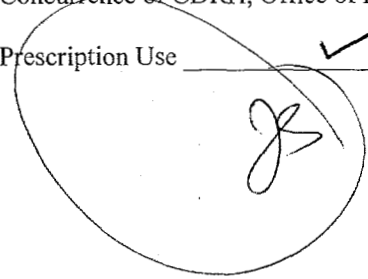
The lens may be prescribed for Daily Wear in not- aphakic persons. The eyecare practitioner may prescribe the contact lens for single use disposable wear.

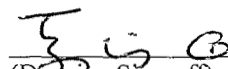
The BIOMEDICS® 52 1-Day (ocufilcon B) Soft (Hydrophilic) UV Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ OR Over-the-counter-use ☐




(Division Sign-off)
Division of Ophthalmic Devices

510(k) Number K020389